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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/122,427 | 07/24/1998 | YIYU ZOU | UTSC584USC2 | 4389 |

7590 10/22/2003
PENNIE & EDMONDS LLP
1155 AVENUE OF THE AMERICAS
NEW YORK, NY 10036-2711

EXAMINER

KISHORE, GOLLAMUDI S

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1615

DATE MAILED: 10/22/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/122,427

Applicant(s)
Zou

Examiner
Gollamudi Kishore, Ph.D

Art Unit
1615



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Aug 8, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-9, 52-55, and 57-84 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-9, 52-55, and 57-84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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DETAILED ACTION

The request for the extension of time, filing under 1.114 and the preliminary amendment all dated 8-8-03 are acknowledged.

Claims included in the prosecution are 1, 4-9, 52-55, 57 and 59-84.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1, 4-9, 52-55 and 66-84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Lyophilization is a specific process which removes only water and volatile organic solvents. The independent claims 1 and 66 recite no water at all. These claims recite two components, namely, a lipid and a non-lipid surfactant. A review of the specification indicates the use of a phospholipid and a surfactant dissolved in t-butanol and water and the this product is then lyophilized. Since said claims are drawn to product by process, the examiner suggests reciting the process steps including t-butanol and water, a phospholipid and the surfactant.

Claim Rejections - 35 U.S.C. § 103

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3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 3-9, 52-55, 57 and 59-84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehta (4,950,432) or (5,811,119), further in view of Unger (5,585,112), Isliker (5,089,602), Hsu (5,653,996) individually or in combination.

Mehta discloses preliposomal powders containing a drug and a mixture of phospholipids. The process of preparation involves dissolving the lipid in t-butanol-water mixture and lyophilization of the mixture into a preliposomal powder. (note the abstract, columns 6-7, Examples and claims).

Mehta does not disclose the use of surfactants such as tweens in the preliposomal preparations.

Unger teaches that non-ionic detergents such as Tweens stabilize the liposome compositions (note col. 25, lines 38-48).

Isliker similarly teaches that Tweens could be used in liposome preparations; the liposome preparations are then lyophilized (Example 11).

Hsu teaches the use of Tweens in liposomal preparations (note col. 5, line 25 et seq.).

In essence, the secondary references all teach the routine practice in the art of the use of Tweens in liposomal preparations. Unger in particular teaches that these are

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liposomal stabilizers. The use of Tweens in the preparations of Mehta would have been obvious to one of ordinary skill in the art since these are stabilizers and routinely used in the art in liposomal preparations.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that none of the references cited by the examiner disclose or suggest a lyophilizate with a lipid and a surfactant, which lyophilizate was made by lyophilizing the composition that did not contain liposomes at the time of lyophilization. The examiner disagrees. It is true that Mehta's compositions does not contain the surfactant during the lyophilization; but it is also true that Mehta's compositions also do not contain liposomes at the time of lyophilization. In response to applicant's arguments that in prior art, one must first make the liposomes and then use physical sizing methods, the examiner points out that instant claim language 'comprising' does not exclude these steps. That is why the examiner has suggested the use of 'consisting essentially of' during the interview in order to place the claims in condition for allowance and this is not done by applicant.

Applicant's arguments with regard to Unger that one of ordinary skill in the art would not be motivated to use sodium lauryl sulfate (SLS) are not found to be persuasive since instant claims do not recite any HLB criteria for the surfactant and the claim language 'non-lipid surfactant' does not exclude either cationic or anionic surfactants such as SLS taught by prior art.

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Applicant's arguments with regard to Isliker and Hsu are not persuasive since these arguments once again are based on the physical sizing of the liposomes and as pointed out above, instant claim language does not exclude the physical sizing.

The examiner once again suggests, as suggested during the interview to recite the language 'consisting essentially of', recite the surfactant as 'non-ionic surfactant' and its ranges and complete process steps (see 112 rejection above) in the independent claims in order to place the claims in condition for allowance.

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5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.

A handwritten signature in black ink, appearing to read 'S Kishore' with a stylized initial 'G' or 'L' on the left.

Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

October 22, 2003